To: **Division of Dockets Management (HFA-305)**
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Att.: **Mr. Jay Crowley**

Submitted as electronic comments to
http://frwebgate.access.gpo.gov/cgi-bin/leaving.cgi?from=leavingFR.html&log=linklog&to=http://www.regulations.gov.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
[Docket No. FDA–2008–N–0661]
Unique Device Identification System;
Public Workshop; Request for Comments
AGENCY: Food and Drug Administration, HHS.
ACTION: Notice of public workshop; request for comments.

Comments supplied by EHIBCC TC, www.ehibcc.com, Febr. 11, 2009
prior to the public workshop Febr. 12, 2009

QUESTION	*ANSWERS*
B. Questions Pertaining to the UDI System 1. Which types of devices or particular devices should be subject to the requirements of a UDI system? Which types of devices or particular devices should be excepted? Section 519(f) of the act states that the Secretary of Health and Human Services may provide ''an exception for a particular device or type of device.'' However, the statute does not specify any criteria for an exception, nor does it describe the scope of an exception.	
a. Should all devices be subject to the requirements of a UDI system? Please explain your reasoning.	*Devices & products, being subject of tracking and tracing.* *UID enables automation and securing processes.*
b. Are there types of devices or particular devices that should receive an exception from the requirements of a UDI system? If so, what types of devices or particular devices should receive an exception and why?	
2. What are the characteristics or aspects necessary to uniquely identify a device? Section 519(f) of the act states that the UDI ''shall adequately identify the device through distribution and use, and may include information on the lot or serial number.'' The statutory language does not describe the characteristics or features that make a device ''unique'' or that ''adequately identify the device through distribution and use.''	
a. What characteristics are needed to uniquely identify a device?	*A UID comprides of a system ID, a unique company code, product code and LOT or Serial number, or as short form* *a system ID, a unique company code and serial number (see UDI concept of DOD)*
b. What core attributes, elements, or characteristics of a device should constitute a minimum data set for a device identifier?	*Data carrier (BC, 2D or RFID) and unique data element according to ISO/IEC 15459 part 4, 6 (under revision) and ISO 22742 linear & 2D symbols for product packaging.*
c. What changes to an attribute, element, or characteristic associated with the unique identification of a device change should result in a new UDI?	*The latest update of ISO/IEC 1549 Unique Identifiers gives guidances how to add features to common UDI's for Items, Packages, Groupings. The bases for Uniqueness is not only a registered company code from GS1 or HIBCC but from evrey Issuing Agency registered under the terms of ISO/IEC 15459, part 2.*
d. Should the UDI include a component that represents package size or packaging level?	*As an option, yes, but not mandatory.*
e. To what extent would or should the list of unique device characteristics vary depending on the type of device?	*It should continue to support variable codification schemes such as, fixed length, variable length, alphan umeric, as long it is unique under global terms.*
3. What should be the UDI's components? a. Could existing standards, such as the standards used by GS1, Health Industry Business Communications Council (HIBCC), or others be used as a model for the UDI system? What are the advantages and	*YES, the advantages are support of best practices and processes and continued optimisation rather than delay's for new implementations on numbering scheme levels. Even RFID would get a smooth path in to UID*

disadvantages of these existing organizations and standards?	*solutions while using existing Unique Identifiers schemes (UII).*
b. Some identification systems currently in use employ a combination of a device identifier (meaning information that identifies the manufacturer, make, and/or model of the device) and a production identifier (meaning information that relates to the lot or serial number). What should the device ''identifier'' component of the UDI cover or contain?	*All of it, if applying.*
c. With respect to the production identifier, we note that the statute says that the UDI may include information on the device's lot or serial number. When should lot or serial number information be required for a device? Are there particular devices for which serial numbers should be required? If yes, what particular devices should be labeled with a serial number? Please explain your reasoning.	*Serial numbers are alway's relevant, if single items need to be handled or supplied.*
d. How might we ensure that UDIs, regardless of the manufacturers or devices associated with those UDIs, are uniform or standardized in their structure or composition? For example, the NDC (National Drug Code) number is always 10 digits long and always presents the labeler code first, followed by the product code and then the package code. Should we limit the number of ways that the UDI can be created or the standards to be used?	
e. How should the UDI be created to ensure that UDIs are unique?	*Global uniqueness only can be achieved, if standards are used. Therefore any UID shall be created according to NDC, ANSI or ISO & IEC standards or sub standards with recognised system identifiers (e.g. ISBT, EUROCODE, ...).*
4. Where should the UDI be placed? What should be the criteria for alternative placement of the UDI? The statute requires the label of devices to bear a unique identifier, unless we require an ''alternative placement'' or provide an exception. Section 201(k) of the act defines ''label'' ''as a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.''	
a. Should we specify where on the label the UDI must appear? If so, where should the UDI appear on the label? Please explain your reasoning.	*UID shall be easily scannable, but the manufacturer shall decide what the best placing should be while designing product and packages.*
i. Should we allow the components of the UDI to be placed separately on the same package or on different levels of packaging? For example, if the UDI consists of a device identifier component and a production identifier component, should we allow the device identifier component of the UDI to be placed in one location and allow the production identifier component to be placed elsewhere on the label or on the device? Please explain your reasoning. As another example, some devices are packaged individually and then packaged again in a larger container (such as a ''shelf pack''). We are aware that some manufacturers would prefer placing both the device identifier component of the UDI and the production identifier component of the UDI on the larger container and placing only the device identifier component of the UDI on the individual packages. Separating UDI components or allowing part (rather than all) of the UDI on package labels may provide for flexibility in product labeling, but also generate confusion as to which UDI to read or scan (if the UDI components are separated) or limit the usefulness of the UDI if a component of the UDI is not present.	*UID should be allowed on different packaging levels if the levels can be identified.*
ii. For barcodes (whether linear or two-dimensional (2D)), should we require the UDI to be expressed in a concatenated manner (whereby the components of the UDI are expressed on the same line adjacent to each other) or in a stacked manner (whereby one component of the UDI rests atop the other component)?	*Both concatenated as stacked manner should be allowed but concatenation shall be the preferred solution targeting to achievable optimum for the future.*
b. Are there devices where we should require the UDI to appear on the device itself (direct part marking)? For example, it might be beneficial to put the UDI on the device itself if the device is re-processed because this	*Direct marked UID's are always beneficial if processed without the packages (e.g. sterilisation, ...)*

might help firms identify or record how many times a particular device has been reprocessed. Similarly, certain single use devices (SUDs) sometimes are reprocessed, so a UDI on the device itself could facilitate the mandatory and voluntary MedWatch reporting relating to such reprocessed devices or facilitate other activities (such as documenting sterilization reprocessing of SUDs and validation studies) associated with SUDs. Conversely, are there devices where the UDI cannot or should not go on the device itself? If so, please describe those devices and explain why the UDI cannot or should not go on the device.	
c. If we allow for ''alternative placement'' of the UDI for some particular devices or types of devices, what should be the general criteria for requiring ''alternative placement'' of the UDI, e.g., such as on the device itself or other location that is not on the label?	*„alternative placement" might be appropriate if standard solutions do not work for particular devices.*
d. What specific challenges or limitations exist regarding ''alternative placement?'' For example, placing a UDI in an automatic identification form on an implantable device may present issues as to whether the automatic identification technology affects the device's integrity or function. As another example, certain devices, such as software, may pose particular challenges for how to label with a UDI.	*Exceptional solutions might by developed for partical environment, if regular solutions would not work.*
5. How should the UDI be presented? We are aware of several automatic identification technologies in use,such as linear bar codes, 2D bar codes, and radio frequency identification. We also note that various FDA regulations and initiatives have required or recommended one or more automatic identification technologies (see 21 CFR 201.25 (bar code label requirement for human drug products); 21 CFR 610.67 (bar code label requirement for biological products); Ref. 2; and section 505D of the act (21 U.S.C. 355e) (regarding ''pharmaceutical security'' and specifying ''promising technologies'' such as RFID (radiofrequency identification), nanotechnology, encryption technologies, and other ''track-and-trace or authentication technologies'')). Therefore:	
a. Should we require human-readable UDIs or automatic identification of UDIs or both? Are there devices where it would be sufficient to have humanreadable UDIs alone? Please explain your reasoning. For example, devices used in a home care setting might not need an automatic identification UDI because the home might not be equipped to read the automatic identifier. Are there situations where we should require both human-readable and automatic identification UDIs? Please explain your reasoning.	*UID's shall be both human readable and automatically scannable. This applies for linear BC and 2D and specifically for RFID.* *If ther is no space for full human interpretation (HRI) the human readable text might be reduced to the key data element (e. g. serial number for surgical instruments or cryols)*
b. Should we specify a particular type of automatic identification technology or should we allow the automatic identification technology to vary depending on the type of device? Should we identify automatic identification standards (as opposed to specific technologies) that can be used? Please explain your reasoning. Specifying a particular type of automatic identification technology would enable hospitals and other parties who might read or use a UDI to make specific investments in scanning or reading equipment, but the technology chosen might not be easily applied to all devices (if we require the UDI to be placed somewhere other than the label.) For this question, we are particularly interested in hearing from parties who might use UDIs as well as entities that may have already adopted or installed device identification systems.	*As type of automatic identification technology the ISO & IEC techniques shall apply such as* *Code 39* *Code 128* *PDF 417* *Data Matrix* *QR Code* *RFID ISO/IEC 18000-3 (HF)and 6C (UHF).* *Hybrid solutions, e.g. Data Matrix & RFID HF are fully in trend providing migration pass for RFID as well and back up.*
c. Should we allow the use of different automatic identification technologies to express different parts of the UDI? For example, the device identifier component might be expressed in a linear bar code and the production identifier component might be expressed in a 2D bar code. Allowing the use of different technologies for different components of the UDI may enable manufacturers to make more efficient use of label space or space on the device itself, but it also could generate confusion as to which identifier to read or scan and could necessitate the purchase of several types of reading and scanning equipment.	*Not the technology, but the data structure shall be used to express different parts of a UID if required. ISO/IEC 15459, part 6 will define „Grouping" of entities which may apply.*
d. Are there existing standards or systems we should consider in establishing the requirements for how the UDI must be presented? For example, we are aware of various standards organizations, such as GS1 and the HIBCC, that exist and have specific formats or specifications for automatic identifiers for products. Should we allow any or all of these standards to be used? developed and maintained? For parties to benefit from UDI information, it would seem necessary for those parties to know, at a minimum, the UDIs that exist, the specific device associated with each UDI, and the information associated with each UDI. It might	*UPN and other data base projects show, that different numbering scemes can coexist in a purly interoparble way. Newer projects as the „HÜAP data base" of Turkey show that registration of existing numberings schemes as GS1 and HIBC would speed up the implementation to a major extend. Specifically entry of products with alphanumeric codes could be done „over night" by means of HIBC as an example. If a specific entry code, e.g. fixed length, would be required it would*

be efficient for one entity to collect the UDIs, associate those UDIs with specific devices, and make the information associated with those UDIs publicly available. However, it is also conceivable (but perhaps less efficient or more costly) that the information could rest with individual manufacturers themselves (rather than FDA) or with a third party or third parties. Consequently: a. How and when should we require UDIs and associated information to be entered into a database? How frequently should we require changes to a UDI or to the information associated with or linked to a UDI to be reported?	*have delayed the project by years and would have coursed unnecessary expentitures.* *Suppliers are responsible to supply traceability data anyway, so it might be enough and mor cost efficiency to link to suppliers sources for his UID's.*
6. How should the UDI Database be developed and maintained? For parties to benefit from UDI information, it would seem necessary for those parties to know, at a minimum, the UDIs that exist, the specific device associated with each UDI, and the information associated with each UDI. It might be efficient for one entity to collect the UDIs, associate those UDIs with specific devices, and make the information associated with those UDIs publicly available. However, it is also conceivable (but perhaps less efficient or more costly) that the information could rest with individual manufacturers themselves (rather than FDA) or with a third party or third parties. Consequently:	*Suppliers are responsible to supply traceability data anyway, so it might be enough and more cost efficiency to link to suppliers sources for his UID's.*
a. How and when should we require UDIs and associated information to be entered into a database? How frequently should we require changes to a UDI or to the information associated with or linked to a UDI to be reported?	*Suppliers are responsible to supply traceability data anyway and for the actualism of the data, so it might be still an option to link to suppliers sources for his UID's as a most effective and cost efficient solution.* *Suppliers may use third parties as well but it would be helpful to get alternative options.*
b. Aside from information that is necessary to uniquely identify a device, what other information (if any) should be part of a UDI system database or otherwise linked to the UDIs?	*The UPN data base showes potential contents.*
c. If variable data (such as a lot or serial number) is necessary to uniquely identify a device, should such data be included in a UDI system database?	*This should be the responsibility of the supplier to avoid redundancy of systems.*
C. Questions Pertaining to Possible Impacts of a UDI System	
Many production situations that might be affected by UDI requirements are complex. In its basic form, a device identifier is a series of digits and/or letters associated with a specific device. At a minimum, a system can be thought of as the set of procedures that allow stakeholders to use an identifier. Through public consultation, however, FDA has found that there are many different views as to the purpose of a UDI system and different opinions about how to describe and implement a UDI system. Because of the diversity of affected devices and manufacturing processes, we expect that affected entities might comply with UDI requirements in a variety of ways. If you respond to the following questions about the costs and benefits of a UDI system, we encourage you to provide as much detail and context as possible. For example, if you identify exceptional costs related to incorporating a UDI in certain production lines, we need to understand the production process details. In addition, we specifically invite small businesses to provide information about a UDI's potential impact.	
1. What is the magnitude of the problem to be addressed by the establishment of a UDI system? Please describe and provide qualitative or quantitative evidence of the incidence of deaths, injuries and illnesses associated with medical devices. What role would a UDI system play in helping to reduce the incidence of such deaths, injuries, and illnesses and how might the structure of a UDI system facilitate this role?	*A UID definetly avoiding potential problems in all cases where individual devices need to be checked or traced even by law.* *UID's show combined benefits of logistical efficienncy and process safets specifically in conjuction with implants, surgical instruments, cryo's/vials's. In this case both standard structures are practiced in Europe: HIBC and ASC (ANS MH10.8.2) according to DIN 66401 UIM: 2005 and HIBC UIM: 2003.*
2. Questions for manufacturers a. *Current practices.* Describe your current practices for applying standards to medical devices, marking identifiers on medical device labeling and managing medical device identifier data. For example, how do you currently use classification standards such as UNSPSC (United Nations Standard Products Service Code), nomenclature standards such as GMDN (Global Medical Device Nomenclature), and identification standards such as GS1 or HIBCC? What percent of your devices are not currently marked with a standardized identifier? Please describe any plans you have to change these practices in the near future.	*I Classification: eClass, GMDN, UNSPSC* *II AIDC standards:* ▪ *ISO 22742 linear and 2d symbols for product packages (ANS ASC, GS1, HIBC)* ▪ *ISO/IEC 15459 Unique Identifiers* ▪ *ANS HIBC 2, HIBCC* ▪ *DIN 66401 Inique Identification Mark* ▪ *ISBT for Blood products* ▪ *EUROCODE for Blood products Europe*
b. *Changing current identifiers.*	*Changes can only be recommended in case of „win*

If you were to add a UDI or change the presentation of your current identifier, please describe your approximate expected capital and operating costs (including labor) to plan for, implement, and apply a UDI to product labeling. To provide context for your estimate, please explain your expected approach to adding a UDI, considering the possibility that a UDI might be a static number (e.g., a manufacturer/product code) or that it might include a variable number (e.g., manufacturer/product/lot code).	*win" situations. If a UID is offered by suppliers according to ANSI and / or ISO it is always a „win – win".* *Changing the labeling scheme e. g. from HIBC to GS1, would course traceability problems and requirements to extent the ERP system. It would not be possible to avoid the previous reference codes but necessary to add another reference. So it would be to manage a „dual numbering system". Cost for changes would apply for:* *+ the traceability system* *+ the data base* *+ the marketing material, catalog, brochures,* *+ entries in existing data bases* *+ changes at the dealers and users side.* *Changing from GS1 to HIBC would not course second reference numbers because HIBC has capacity for GTINs but not vice versa.* *Adding ASC system (Data Identifiers) e.g. for Unique Serial Number for smallest devices would not change a system but add features.*
c. *Encoding variable data.* If you were to add a UDI bar code with variable data (such as lot or serial number) to medical device labeling, please describe how you would print the variable bar coded information. For example, do you foresee using on-line label printing, other in-house printing, or contract printers to add a UDI bar code?	*Variable data printing is a tradition with HIBC since 20 years.* *Specifically serialisation can be a challange for higher volume products but not for smaller series and individual products.*
d. *Production line impacts.* Considering your operations, are there products where adding a UDI (human readable or barcode; static or variable) to labeling would not be feasible without major capital investment or overhauling production lines? If so, please describe the products and suggest alternatives or solutions.	
e. *Small devices and small packages.* A UDI could present a challenge for some small packages. What percentage of your product line consists of devices whose small size could make placing a UDI on a label problematic? Of those devices identified, what ''alternative placement'' of the UDI would be feasible? Please explain your reasoning. Please describe the nature of the problems and costs to solve such problems. Please suggest alternatives or solutions.	*Suggestion for smallest devices:* *For very small devices being subject to traceability, DIN 66401 based on HIBC UIM solution was developed where a unique code amounts to 3.2x3.2mm as a minimum. It includes „Issuing Agency Code (IAC), Labeler ID (LIC/CIN) and Serial number embaddes in DataMatrix (or QR).*
3. Questions for hospitals, nursing homes, and clinics	
a. *Using a UDI.* If UDIs were placed on at least some medical devices, what functions could a UDI serve in your institution?	
b. *Expenses.* What expenses do you foresee in attempting to capture and use UDIs placed on medical devices? If you foresee using UDIs, how would you modify operations in your facility?	
c. *Adverse event reporting and recalls.* How would capturing the UDI change your recall management or adverse event reporting? For recalls or adverse events involving the most serious device malfunctions or failures, how have problems in device identification impaired your recall management or adverse event reporting? Please describe the magnitude of the problems you have encountered.	